December 23, 2003

Sarah Loftus McLallen
Manager, CHEMSTAR
The American Chemistry Council Petroleum Additives Panel
Health, Environmental, and Regulatory Task Group
1300 Wilson Boulevard
Arlington, VA 22209

Dear Ms. McLallen:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for Isooctadecanoic Acid Reaction Products w/ TEPA posted on the ChemRTK HPV Challenge Program Web site on August 19, 2003. I commend The American Chemistry Council Petroleum Additives Panel Health, Environmental, and Regulatory Task Group for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA will post this letter and the enclosed comments on the HPV Challenge Web site within the next few days. As noted in the comments, we ask that the Panel advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission. Please send any electronic revisions or comments to the following e-mail addresses: oppt.ncic@epa.gov and chem.rtk@epa.gov.

If you have any questions about this response, please contact Richard Hefter, Chief of the HPV Chemicals Branch, at 202-564-7649. Submit questions about the HPV Challenge Program through the "Contact Us" link on the HPV Challenge Program Web site pages or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

-S-

Oscar Hernandez, Director
Risk Assessment Division

Enclosure

cc: W. Penberthy
M. E. Weber

EPA Comments on Chemical RTK HPV Challenge Submission:
Isooctadecanoic Acid Reaction Products with TEPA

Summary of EPA Comments

The sponsor, the American Chemistry Council Petroleum Additives Panel, submitted a test plan and robust summaries to EPA for isooctadecanoic acid reaction products with TEPA (CAS No. 68784-17-8) dated August 5, 2003. EPA posted the submission on the ChemRTK HPV Challenge Web site on August 19, 2003.

EPA has reviewed this submission and has reached the following conclusions:

1. Chemical Definition. The submitter needs to discuss factors that lead to differences in the composition of these reaction products and whether one product is more common than the others. Also, if possible, the submitter needs to conduct the proposed tests on the most typical composition.

2. Physicochemical Properties. The submitter's test plan for physicochemical properties is adequate for the purposes of the HPV Challenge Program.

3. Environmental Fate. The data provided for biodegradation are adequate for the purposes of the HPV Challenge Program. The submitter's proposal for estimating photodegradation and providing a technical discussion of hydrolysis is acceptable. However, EPA recommends that the submitter use a level III model when running its fugacity model.

4. Health Effects. EPA agrees with the submitter's proposal to conduct a combined repeated-dose/reproductive/developmental toxicity screening test and an *in vitro* chromosomal aberrations test.

5. Ecological Effects. EPA reserves judgement on the adequacy of the acute toxicity data on fish, aquatic invertebrate, and aquatic plants pending receipt of the results of proposed water solubility tests.

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.

EPA Comments on the Isooctadecanoic Acid Reaction Products With Tepa Challenge Submission

Test Plan

Physicochemical Properties (melting point, boiling point, vapor pressure, partition coefficient and water solubility)

The submitter indicates that this substance is a product formed from a reaction that occurs in a solvent composed of highly refined lubricant base oil. Thus the "active ingredients" are not isolated during the life cycle of this substance. Therefore, the submitter's proposal to provide estimated boiling point, vapor pressure, and octanol/water partition coefficient values is adequate for the purposes of the HPV Challenge Program.

Water solubility. The submitter's proposal to provide experimental (measured) water solubility data is acceptable for the purposes of the HPV Challenge Program.

Environmental Fate (photodegradation, stability in water, biodegradation, fugacity)

The data provided by the submitter for biodegradation are adequate for the purposes of the HPV Challenge Program. The submitter's proposal to provide an estimate for photodegradation and a technical discussion of water stability is acceptable.

Fugacity. The submitter proposes to evaluate fugacity using a level I fugacity model. Although EPA previously recommended the use of the level I model, EPA now recommends the use of the level III model. EPA believes that values based on a level III fugacity model are more realistic and useful for estimating a chemical's fate in the environment. The submitter should not use estimated physicochemical data as inputs when running the model, as this introduces uncertainties that become magnified in modeling applications.

Health Effects (acute toxicity, repeated-dose toxicity, genetic toxicity, and reproductive/developmental toxicity)

Adequate data are available for acute toxicity and gene mutations for the purposes of the HPV Challenge Program. EPA agrees with the submitter's proposal to conduct a combined repeated-dose/ reproductive/ developmental toxicity screening test according to OECD TG 422 and an *in vitro* chromosomal aberrations test according to OECD TG 473.

Ecological Effects (fish, invertebrates, and algae)

EPA reserves judgement on the adequacy of the acute toxicity data on fish, aquatic invertebrate, and aquatic plants pending receipt of the results of proposed water solubility tests. The rationale is that the nominal concentrations used in the tests may be higher than the water solubility limit of this chemical and the data are acceptable only if the measured values are below the water solubility limits.

Followup Activity

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.